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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,451	03/24/2004	Wing Cheung	38081-00036	8517

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PRESTON GATES ELLIS & ROUVELAS MEEDS LLP
1735 NEW YORK AVENUE, NW, SUITE 500
WASHINGTON, DC 20006

EXAMINER	
MORAN, MARJORIE A	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 06/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/807,451	CHEUNG ET AL.	
	Examiner	Art Unit	
	Marjorie A. Moran	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *204-323* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *204-323* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 March 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/20/04*. 3/24/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Information Disclosure Statement

The IDS filed 12/20/04 has been considered in full.

Specification

The amendment filed 3/24/05 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the incorporation by reference of 09/569,612 on page 1 is new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 234-263 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 234 recites the limitation "the one or more EPO dosages" in step (c). There is insufficient antecedent basis for this limitation in the claim, therefore the claim is indefinite. Claims 235-263 depend from claim 234 and are therefore also indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 204-215, 217, 219-221, 223-225, 227, 231, 234-245, 247, 249-251, 254-255, 257, 259-261, 264-275, 277, 279-281, 283-285, 287, 291, 294-305, 307, 309-311, 313-315, 317, 321 are rejected under 35 U.S.C. 102(a) as being anticipated by CHEUNG et al. (IDS ref: Clin. Pharm. Ther. (10/1998) vol. 64, pp. 412-423).

CHEUNG teaches a method of choosing an EPO dosing regimen which maintains a serum EPO concentration above an endogenous predose level for 5-8 days, or at least 22 days wherein a PK/PD profile is used to select the dosage regiment that provides the desired PK and/or PD response (pp. 413 and 420), thereby anticipating claims 204, 234, 264, and 294. CHEUNG teaches that his dosing regiment also increases reticulocyte number for at least 22 days (p. 420), thereby anticipating claims 205-207, 235-237, 265-267, and 295-297. CHEUNG teaches administration of epoetin alfa once a week at 600 IU/kg (p. 420), and teaches administration of 40,000-80,000 IU (p. 414), and 900 IU/kg (abstract), thereby anticipating claims 208-215, 217, 219, 238-245, 247, 249, 268-275, 277, 279, 298-305, 307, and 309. CHEUNG further teaches that his dosage regimen is used to treat anemia, specifically anemia associated with chemotherapy, and with zidovudine treatment of AIDS patients (p. 420), and

teaches both intravenous and subcutaneous dosing (p. 413), thereby anticipating claims 220-221, 223-225, 227, 231, 250-251, 254-255, 257, 259-261, 280-281, 283-285, 287, 291, 310-311, 313-315, 317, and 321.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 216-219, 232-233, 246-249, 262-263, 276-279, 292-293, 306-309, and 322-323 are rejected under 35 U.S.C. 103(a) as being unpatentable over CHEUNG et al. (IDS ref: Clin. Pharm. Ther. (10/1998) vol. 64, pp. 412-423), as applied to claims 204-215, 217, 219-221, 223-225, 227, 231, 234-245, 247, 249-251, 254-255, 257, 259-

261, 264-275, 277, 279-281, 283-285, 287, 291, 294-305, 307, 309-311, 313-315, 317, 321 above, in view of FIBI et al. (EP 902085, 3/17/1999).

CHEUNG teaches a method of choosing an EPO dosing regimen which maintains a serum EPO concentration above an endogenous predose level for 5-8 days, or at least 22 days, using recombinant epoietin alfa, as set forth above. CHEUNG does not teach an EPO analog or isoform, or an EPO with a modified glycosylation pattern.

FIBI teaches an EPO analog with altered glycosylation pattern (abstract). FIBI's hyperglycosylated EPO is darbepoetin alpha.

It would have been obvious to one of ordinary skill in the art at the time of invention to have administered the hyperglycosylated EPO of FIBI in the method of CHEUNG where the motivation would have been to use an EPO with improved half-life and biological activity, as taught by FIBI (p. 3, lines 19-22).

Claims 211, 226, 241, 256, 271, 286, 301, and 316 are rejected under 35 U.S.C. 103(a) as being unpatentable over CHEUNG et al. (IDS ref: Clin. Pharm. Ther. (10/1998) vol. 64, pp. 412-423), as applied to claims 204-215, 217, 219-221, 223-225, 227, 231, 234-245, 247, 249-251, 254-255, 257, 259-261, 264-275, 277, 279-281, 283-285, 287, 291, 294-305, 307, 309-311, 313-315, 317, 321 above, in view of SHINSHI et al. (IDS ref: JP 02096353).

CHEUNG teaches a method of choosing an EPO dosing regimen which maintains a serum EPO concentration above an endogenous predose level for 5-8

days, or at least 22 days, wherein anemia related to chemotherapy may be treated, as set forth above. CHEUNG does not teach dosing once every two weeks nor anemia related to cisplatin chemotherapy.

SHINSHI teaches a method of dosing with EPO to achieve a desired PK/PD response, wherein EPO is administered at least once every two weeks and may be administered to patients suffering from cisplatin-related chemotherapy (abstract).

It would have been obvious to one of ordinary skill in the art at the time of invention to have chosen a dosing regimen for any chemotherapy-induced anemia, specifically that caused by cisplatin, as taught by SHINSHI, using the method of CHEUNG, where the motivation would have been to relive a side-effect of the chemotherapy, as taught by both CHEUNG and SHINSHI. It would further have been obvious to have timed the dosage in the method of CHEUNG at once every two weeks, as taught by SHINSHI, where the motivation would have been to increase the time between doses to improve the convenience of administration, as taught by CHEUNG (p. 421-422).

Claims 222, 228, 230, 252, 258, 260, 282, 288, 310, 312, and 318 are rejected under 35 U.S.C. 103(a) as being unpatentable over CHEUNG et al. (IDS ref: Clin. Pharm. Ther. (10/1998) vol. 64, pp. 412-423), as applied to claims 204-215, 217, 219-221, 223-225, 227, 231, 234-245, 247, 249-251, 254-255, 257, 259-261, 264-275, 277, 279-281, 283-285, 287, 291, 294-305, 307, 309-311, 313-315, 317, 321 above, in view

of SALMONSON et al. (IDS ref: Scan. J. Urol. Nephrol. (1990) vol. 0, suppl. 129, pp. 1-66).

CHEUNG teaches a method of choosing an EPO dosing regimen which maintains a serum EPO concentration above an endogenous predose level for 5-8 days, or at least 22 days, for treatment of anemia, as set forth above. CHEUNG does not teach anemia related to renal failure, blood donation or arthritis.

SALMONSON teaches a method of determining a dosage of EPO using PK/PD information wherein conditions to be treated with his dosing regiment include rheumatoid arthritis, various renal failure associated diseases, and anemia due to blood donation or transfusion (pp. 22-23).

It would have been obvious to one of ordinary skill in the art at the time of invention to have chosen a dosing regimen for any of the disorders of SALMONSON using the method of CHEUNG where the motivation would have been to maintain an enhanced "steady-state" of red blood cells in order to overcome the anemia, as taught by SALMONSON (p. 31).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims (204-233), (234-263), (264-293), and (294-323) are each rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 6,747,002 in view of CHEUNG et al. (IDS ref: Clin. Pharm. Ther. (10/1998) vol. 64, pp. 412-423).

Each set of instant claims recites choosing a dosage regimen or a PK or PD response, using a PK/PD model to determine a PK and/or PD profile or regimen, and selecting a regimen which produces a desired response, wherein the regimen maintains an EPO serum concentration above a predose level for about 5-30 days.

Claims 1-30 of '002 recite a method of administering an EPO dose according to a dosing regimen and recite dosing limitations, EPO limitations, and anemia limitations similar to those of the pending claims. Claims 1-30 do not recite selecting a desired PK and/or PD response or using a PK/PD model to determine the dosage to be administered.

CHEUNG teaches using a PK/PD model to choose a dosing regiment to give a desired response, wherein the dosing regimen chosen maintains an EPO serum level above endogenous pre-dose levels for at least 22 days, as set forth above.

It would have been obvious to one of ordinary skill in the art at the time of invention to have used the PK/PD model of CHEUNG to establish the dosing regimen in

the claims of '002 where the motivation would have been to choose an effective/optimal dosing regime for stimulating a reticulocyte response, as taught by CHEUNG (abstract).

Conclusion

Claims 204-323 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon,Wed: 7-1:30; Tue,Thur: 7:30-6; Fri 7-3:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran
Primary Examiner
Art Unit 1631

Marjorie A. Moran
6/10/05